#45

Transmission Control Records

This is the output equivalent of the input TRANSMITTER RECORD and includes counts of records received, records rejected, error records returned, records posted to the National Directory of New Hires, records posted to the Suspense File and up to five Error Codes pertaining to the transmission level error conditions encountered.

Data Records

Each output version of the input DATA RECORD had appended to it up to five record level error codes that indicate the nature of the error encountered during editing. It also contains a Social Security Number Verification Indicator that indicates whether multiple valid SSNs were encountered during the SSN verification process. In addition, a corrected SSN is returned if during the SSN verification process the supplied SSN was determined to be incorrect and the verification procedure was able to provide the correct SSN.

Total Records

No transmission total records will be returned to the submitting State or federal agency

Additional Information

ACF is requesting that OMB grant a 180 day approval for this information collection under procedures for emergency processing by August 15, 1997. A copy of this information collection, with applicable supporting documentation, may be obtained by calling the Administration for Children and Families, Reports Clearance Officer, Robert Driscoll at (202) 410–9313 or (202) 401–6465. Internet address: rdriscoll@acf.dhhs.gov

Comments and questions about the information collection described above should be directed to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for ACF, Office of Management and Budget, Paperwork Reduction Project, 725 17th Street N.W., Washington, D.C. 20503, (202) 395–7316.

Dated: July 10, 1997.

Robert Driscoll,

Reports Clearance Officer.

[FR Doc. 97–18675 Filed 7–17–97; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97E–0077]

Determination of Regulatory Review Period for Purposes of Patent Extension; GLYSET™

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for GLYSET™ and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product GLYSET™ (miglitol). GLYSET™ is indicated as an adjunct to diet to improve glycemic control in patients with non-insulin-dependent diabetes mellitus whose hyperglycemia cannot be managed with diet alone. GLYSET™ may also be used in combination with a sulfonylurea when diet plus either GLYSET™ or a sulfonylurea alone do not result in adequate glycemic control. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for GLYSET™ (U.S. Patent No. 4,639,436) from Bayer Aktiengesellschaft, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated March 21, 1997, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of GLYSET™ represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for GLYSET™ is 4,900 days. Of this time, 4,544 days occurred during the testing phase of the regulatory review period, while 356 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* July 22, 1983. FDA has verified the applicant's claim that the date that the investigational new drug application became effective was on July 22, 1983.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act:* December 29, 1995. FDA has verified the applicant's claim that the new drug application (NDA) for GLYSET™ (NDA 20–682) was initially submitted on December 29, 1995.

3. *The date the application was approved:* December 18, 1996. FDA has verified the applicant's claim that NDA

20-682 was approved on December 18, 1996.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,827 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before September 16, 1997, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before January 14, 1998, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 8, 1997.

Allen B. Duncan,

Acting Associate Commissioner for Health Affairs.

[FR Doc. 97-18909 Filed 7-17-97; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97E-0067]

Determination of Regulatory Review Period for Purposes of Patent Extension; ZYFLO™

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ZYFLO™ and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product ZYFLO™ (zileuton). ZYFLO™ is indicated for the prophylaxis and chronic treatment of asthma in adults and children 12 years of age and older. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ZYFLO™ (U.S. Patent No. 4,873,259) from Abbott Laboratories, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated March 12, 1997, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of ZYFLO™ represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for ZYFLO™ is 3,329 days. Of this time, 2,454 days occurred during the testing phase of the regulatory review period, while 875 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* October 31, 1987. The applicant claims October 30, 1987, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was October 31, 1987, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act:* July 19, 1994. The applicant claims July 18, 1994, as the date the new drug application (NDA) for ZYFLO™ (NDA 20-471) was initially submitted. However, FDA records indicate that NDA 20-471 was submitted on July 19, 1994.

3. *The date the application was approved:* December 9, 1996. FDA has verified the applicant's claim that NDA 20-471 was approved on December 9, 1996.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,398 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before September 16, 1997 submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before January 14, 1998 for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review